REMARKS

Claim 5 was amended to correct the spelling of "gelatin."

Claim 10 was amended to add a period at the end of the claim.

It is submitted that no new matter has been introduced by the foregoing amendments. Approval and entry of the amendments is respectfully solicited

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page(s) is/are captioned "Version with markings to show changes made."

Objection

Claims 5 and 10 were objected to for containing "informalities." (April 1, 2002 Office Action ("OA") at 2.) In particular, the Examiner noted that the word "gelatin" was spelled incorrectly n claim 5 and claim 10 did not contain a period at the end of the claim. As noted above, claims 5 and 10 have been amended to remedy the "informalities" and, it is submitted, the objection is rendered moot and should be withdrawn.

Obviousness Rejection

Claims 1-16 were rejected under 35 USC §103(a) as being unpatentable over Lee (U.S. Pat. No. 6,060,078) ("Lee") in view of Mehta (U.S. Patent No. 4,800,087). (Paper No. 1 at 2.)

For the reasons set forth below the rejection, respectfully is traversed.

Lee discloses a chewable tablet having a core containing a medicament in a state of jelly or chewable base; and an outer layer of chewable base wrapping the core. (Col. 1, ln. 65 – col. 2, ln. 3.) The medicament in the core was disclosed as being of bitter taste. (Col. 2, lns. 4-5.) Acetaminophen was disclosed as possibly being contained in the core. (Col. 2, lines 9-18.) According to Lee, the jelly base of the core, which contains the above medicament in a state of jelly, may be selected from the group consisting of pectin, sorbitol, maltitol, isomalt, liquid glucose, sugar, citric acid and a flavoring agent. (Col. 2, lns 29-32.) According to Lee, the chewable tablet provides taste mask effect to a bitter tasty medicament, which is contained in the medicament, and better chewing property and taste than the conventional tablets by means of an outer tasty chewable base. (Col. 3, lns. 54-57.)

Mehta discloses a pharmaceutical composition having (1) a pharmaceutical core which is further comprised of a pharmaceutically active dose of a compound and, (2) a microencapsulating polymer which coats the pharmaceutical core and is capable of taste-masking the active compound. (Abst.) Mehta was concerned with taste-masked pharmaceuticals and to taste-masked pharmaceuticals capable of being chewed without producing a bitter taste. (Col. 1, lns. 6-8.) Mehta discloses that the formulation includes a tablet which further includes acetaminophen coated with a combination of polymers. (Col. 1, lns. 18-21.) According to Mehta, the acetaminophen chewable tablets do not exhibit the bitter and unpleasant taste normally associated with acetaminophen. (Col. 1, lns. 21-23.)

Mehta posits that, from a manufacturing cost standpoint, it is desirable to have chewable, taste-masked microcapsules that are large (0.25-1 mm in diameter), because larger microcapsules are easier to manufacture and package, and are less expensive to produce than are smaller microcapsules. (Col. 2, lns. 18-22.) However, according to Mehta, an increase in size makes fracture during chewing and the release of drug from the microcapsule more likely to occur especially when there is an inadequate amount of plasticizer or other component included to provide elasticity. (Col. 2, lns. 23-27.) Mehta theorizes that a larger sized microcapsule requires greater elasticity to minimize the likelihood that a fracture will occur and active agent will be released. (Col. 2, lns. 27-30.) According to Mehta, there is a need in the art of pharmaceutical formulation to provide encapsulating coatings capable of being formulated into chewable microcapsules as large as about 1.5 mm., **that will not release drugs during chewing**. (Col. 2, lns. 30-34.) Metha listed several objects of the invention, which included chewable taste-masked formulation that can **provide immediate release of an active compound as soon as it reaches the stomach** and delayed release of the active agent in the upper intestinal tract (duodenum, jejunum, or ileum) or sustained release of the active agent. (Col. 2, lns. 56-64.)

According to Mehta, the taste-masked microcapsules include (1) a polymeric coating that may provide **chewable taste-masked characteristics** and (2) a pharmaceutical core of active ingredients. (Col. 4, lns. 4-8.) Mehta also discloses that once the pharmaceutical core has been coated it can then be encapsulated in a hard gelatin capsule, further coated with candy coating or pressed into tablet form or presented as a standard dosage form well known

in the pharmaceutical formulation art. (Col. 9, lns. 35-39.) Metha's preferred uncoated acetaminophen particle size range is 150 to 300 microns. (Col. 10, lns. 45-46.)

In making the rejection, the Examiner asserted that "Mehta teaches a chewable, taste-masked pharmaceutical dosage form, preferably in the form of a tablet." (OA at 2.) The Examiner contended that "the components of this dosage form consist of taste-masked microcapsules, which may then be prepared as chewable tablets." The Examiner also asserted that the microcapsules themselves comprise a polymeric coating that masks the taste of. the active ingredient, and a pharmaceutical core." (OA at 3.) The Examiner also contended that "[a]cetaminophen and ibuprofen are listed among suitable drugs for use in the reference." The Examiner further asserted that "[d]iluents acceptable for use in the microcapsule core include gelatin." The Examiner also stated that "[i]n the given examples, the preferred size of the uncoated acetaminophen particles used lies in the range of 150 to 300 microns and a rationale for such a limitation is given as well." The Examiner further stated that "[t]he reference also teaches that the coated pharmaceutical cores may then be encapsulated in hard gelatin capsule or further coated with candy." The Examiner acknowledged, however, that Mehta differs from the presently claimed invention because "Mehta does not teach the use of a pectin-based core."

To fill the acknowledged gap, the Examiner relied upon Lee as teaching "a chewable pharmaceutical dosage form consisting of a core containing an active ingredient and an outer layer. (*Id.*) The Examiner asserted that the core may be in the form of a jelly, with the base of the jelly selected from a group that includes pectin." The Examiner contended that gelatin may be used in either the core or outer layer to maintain hardness and hardness property of the dosage form. The Examiner further contended that the outer layer may take a variety of forms, including hard candy. Additionally, the Examiner states that acetaminophen is listed as a possible active ingredient in the core.

The Examiner reasoned that the limitation of the weight ratio of the drug particles to the outershell was not critical. It was the Examiner's stated opinion that the inventions of the prior art perform their intended use, that is, the taste masking and delivery of active substances, without explicitly possessing such characteristics. Also, it was the Examiner's stated opinion that the brittleness limitation presented in claim 6 is also not critical for the same reason.

The Examiner then concluded that "it would have been obvious to one of ordinary skill in the art to combine the teachings of Mehta and Lee in order to produce a chewable dosage form, consisting of a brittle outer shell and a soft core, which masks the taste of the bitter active ingredients such as acetaminophen and ibuprofen; provides a pleasant mouth-feel; and is convenient to consume, thereby increasing the likelihood of patient compliance. (OA at 4.)

Initially, it is noted that the rejection was over Lee in view of Mehta. However, in setting forth the reasoning for the rejection, the Examiner appears to have made the rejection over Mehta in view of Lee. The record is not clear as to the precise basis is for the instant rejection. The Examiner is asked to clarify the rejection in the next paper issued in the captioned application.

Additionally, the Examiner asserted that the claimed invention was "a chewable dosage form, consisting of a brittle outer shell and a soft core." However, such an interpretation is not commensurate in scope with the claims as present. Indeed, the claims use the open transition term "comprising" rather than the closed transition term "consisting of." The Examiner is asked to correct the record in the next paper issued in the captioned application.

Regardless of whether the Examiner relied upon Lee in view of Mehta or Mehta in view of Lee in making out the rejection, both documents are concerned with solving the problem of taste masking. Mehta disclosed a technique for taste-masking acetaminophen particles that were between 150 and 300 microns. Mehta's disclosure resulted in coated particles designed to prevent **release drugs during chewing.** It appears that such prevention avoided contact of acetaminophen in the mouth during chewing, thereby avoiding a bitter taste.

While Mehta did disclose a "rationale for such a limitation" in the size of the acetaminophen particles, it is submitted that one of ordinary skill in the art would be motivated to use large particles, e.g., particles from 150 to 300 microns, when one wished to produce coated particles. One of ordinary skill in the art would know the difficulties associated with coating small particles, e.g., particles from 10 to 40 microns. Additionally, its is not seen where Mehta disclosed any facts to indicate that texture masking was also addressed.

It appears that Lee disclosed a different technique for taste-masking. Lee discloses a core containing a medicament in a state of jelly or chewable base, and an outerlayer of chewable base wrapping the core. Lee did not disclose that the particles used therein were coated. It is submitted that one of ordinary skill in the art would have disclosed coated particles if coated particles were in fact used to make the disclosed composition. Lee therefore used uncoated particles. Because Lee used uncoated particles, there appears to be no motivation for one seeking to solve the problem of taste masking that Mehta and Lee were attempting to solve by using large particles because such particles would necessarily introduce a new problem, i.e., grittiness, into the composition. Additionally, it is not seen where Mehta disclosed any facts to indicate that texture masking was also addressed.

Obviousness cannot be based upon speculation. Nor can obviousness be based upon possibilities or probabilities. Obviousness *must* be based upon facts, "cold hard facts." When a conclusion of obviousness is not based upon facts, it cannot stand.

Contrary to the Examiner's assertions, the instant application is not concerned with solving the problem of taste-masking only. Indeed as affirmatively stated in paragraph 11 of the instant application, the presently claimed invention is directed to solving the problem of **both** taste-masking and texture-masking. It is respectfully submitted that one of ordinary skill in the art would not be motivated to coat the particles of Lee given the difficulties known in the art for coating small particles, e.g., powders.

Moreover, most if not all inventions arise from a combination of old elements. *In re Kotzab*, 55 USPQ2d 1313 (Fed. Cir. 2000). Every element of a claimed invention may often be found in cited in the prior art. *Id.* However, identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention. *Id.* Rather, to establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion, or teaching of the desirability of making the specific combination that was made by the applicant. *Id.*

With all due respect, the rejections made under 35 U.S.C. §103(a) by the Examiner are merely recitations of claim elements identified in different documents. In fact, the Examiner has not made any showing as to why one faced with the problem of taste-masking and texture-masking would look to documents concerned with only taste-masking. There is no specific showing in this record as to any motivation or reason why the cited documents

should be combined. For this additional reason, the rejection is improper and should be withdrawn.

In view of the forgoing, reconsideration of the Examiner's position vis-à-vis the weight ratio of drug particles to outershell and the brittleness limitation of claim 6.

Accordingly, for the reasons set forth above, entry of the amendments, withdrawal of the rejections, and allowance of the claims is respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claim 5 was amended as follows:

5. (Amended) An oral dosage form of claim 1, wherein the soft core is gelaetin based.

Claim 10 was amended as follows:

10. (Amended) An oral dosage form of claim 8, wherein the active agent is ibuprofen.